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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation LISA HYDE and MARK HYDE, a married couple, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	No. MD-15-02641-PHX-DGC **PLAINTIFFS' MOTION *IN LIMINE #4* TO EXCLUDE OR LIMIT ARGUMENT AND EVIDENCE REGARDING BARD'S G2X INFORMATION FOR USE** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

MEMORAUNDM OF LAW IN SUPPORT

Defendants' motion for partial summary judgement, with respect to Plaintiffs' claims for failure to warn, was granted on July 26, 2018. (Doc. 12007.) At trial, evidence to support Plaintiffs' negligent and strict liability failure to warn claims, is no longer necessary.[1] Plaintiffs must only prove Bard's defective design caused Mrs. Hyde's injuries. *Id*. Therefore, Defendants will not need to rebut with the learned intermediary defense with evidence regarding alleged, well-known and inherent risks of the product like in *Booker* and

[1] Wis. Stat. Ann. §895.047(1); *See Kessel v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211-12 (Wis. Ct. App. 2006); *see also Lexington Ins. Co. v. Whesco Grp., Inc.*, No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013).

Jones. The focus of Plaintiffs' case will be on the product design and whether or not it departed from its intended design, or the risk of foreseeable harm, known or not, would have been reduced by the adoption of a reasonable alternative design, and the omission of an alternative design rendered the design not reasonably safe. Wis. Stat. Ann. §895.047(1)(a). As such, the instructions for use ("IFU"), also known as general labeling provisions, are no longer relevant in the *Hyde* case.[2]

The information contained in the G2X IFU, list of equipment, directions for use, indications for use, removal procedure, clinical experience regarding removal, precautions, warnings, potential complications, and contradictions, is the evidentiary focus in a failure to warn claim, however, without a failure to warn claim, any probative value of the IFU is rendered moot.[3] All that remains is irrelevant, prejudicial, confusing, misleading, and time consuming "value" to Defendants.[4]

Nothing in the IFU provides support or addresses whether Bard departed from its intended design or whether or not the foreseeable risks could have been reduced or avoided by a reasonable alternative design, the omission of which rendered the design not reasonably safe. Wis. Stat. Ann. § 895.047(1)(a). A physician's knowledge or lack of knowledge about risks and complications associated with the product and contained in the "warnings" and "potential complications" sections of the IFU, and whether or not the physician shared

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[2] Medical device manufacturers include an IFU in the product packaging to offer guidance for physicians implanting its product and provide information the manufacturer has deemed relevant for proper use.

[3] In the event Defendants argue the IFU is relevant to present "clinical experience" regarding removal study results, Plaintiff advises the Court that the "clinical experience" section is a summary of the Everest Study. The "Clinical experience" in the IFU focuses on removal results and complications observed, it represents 3 paragraphs of an 11-page document; this evidence is unfairly prejudicial to Plaintiff based on the arguments *supra*. Further, this evidence would be cumulative as 14 exhibits in *Booker* and 11 exhibits *Jones* were admitted regarding the Everest Study results, including the Final Study Report, trial exhibit 5290, which was admitted in both trials and contains the exact results presented in the IFU.

[4] *See* Exhibit A, G2X IFU. In light of the pending issues regarding Defendants claims that the product at issue is an Eclipse filter, Plaintiffs submit that the Eclipse IFU should also be excluded for the same reasons stated herein.

details regarding these risks and complications with the Plaintiff, will have no effect on the jury deciding if Mrs. Hyde's filter was defectively designed. That is, Mrs. Hyde is the ultimate consumer of her Bard IVC filter. See, *Green v. Smith & Nephew AHP, Inc.*, 245 Wis. 2d 772, 825-26 (Wis. 2001).

Without a failure to warn claim, there is no fact of consequence in this action that the IFU will prove or disprove. Fed. R. Evid. 401, 402. Bard should not be allowed to distract from the facts relevant to Mrs. Hyde's case; her injuries, the G2X design, and Bard's liability. Moreover, any alleged relevance is substantially outweighed by the unfair prejudice to Mrs. Hyde. The jury will be confused and misled into believing that the defendants have a defense to a claim that no longer exists, i.e., that the IFU's "warnings" section provided adequate or reasonable warning to Mrs. Hyde or her physician when the defense to a failure to warn claim is not available to Bard, including the learned intermediary defense which is steeped in the failure to warn concept. Bard's IFUs do not address, for example, a safer alternative design. As such, Bard's IFUs are not relevant and should be excluded to not confuse or mislead the jury and prejudice Mrs. Hyde's existing claims. Fed. R. Evid. 401, 402, 403, 801, 802.

RESPECTFULLY SUBMITTED this 10th day of August 2018.

GALLAGHER & KENNEDY, P.A.

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of August 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine